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| 09/885,247 | 07/13/2000 | Michael Zasloff | 036870-5062-01 | 5537 |
| 9629 7590 01/04/2008 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004 | | | | |
| EXAMINER CHONG, YONG SOO | | | | |
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL ZASLOFF,
JON WILLIAMS, WILLIAM KINNEY,
MARK ANDERSON, and
MIKE McLANE,

Appellants

Appeal 2007-4261
Application 09/885,247¹
Technology Center 1600

Decided: January 4, 2008

Before ADRIENE LEPIANE HANLON, CAROL A. SPIEGEL, and
LORA M. GREEN, *Administrative Patent Judges*.

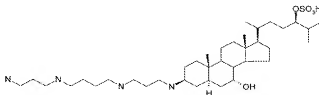
SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Application 09/885,247 was filed 13 July 2000 as a continuation-in-part of Application 08/857,288, filed 16 May 1997 and issued 7 November 2000 as Patent 6,143,738, which claims priority benefit of Provisional Application 60/017,627, filed 17 May 1996, and of Provisional Application 60/029,541, filed 1 November 1996. The real party-in-interest is said to be Genaera Corporation (Appeal Brief filed 27 November 2006 ("Br." 2)).

This is an *ex parte* appeal under 35 U.S.C. § 134(a) from the final rejection of claims 14-30, all of the claims pending in this Application. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

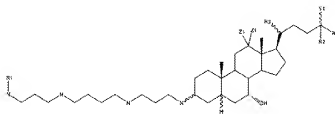
The subject matter on appeal relates to methods of lowering blood cholesterol or glucose levels by administering a known compound, i.e., an aminosterol known as "compound 1436" or a defined analog thereof. Compound 1436 is defined as ('247 Specification 4:14; Figure 1)



Claim 14 is illustrative and reads as follows (Br. 14):

14. A method for reducing blood cholesterol levels in a mammal suffering from hypercholesteremia, comprising

administering to the mammal an effective amount of a composition comprising a compound of the following formula:



wherein

R₁ = H or C₁-C₆ alkyl;

R₂ = H or C₁-C₆ alkyl-X where X = H, OH, Cl, Br, I or F;

R₃ = H or C₁-C₃ alkyl;

R₄ = H or C₁-C₃ alkyl;

Y₁ = CO₂H, NHSO₂CF₃, SO₃H, PO₃H₂, OSO₃H, CF₃ or F; and

Z₁ = H or OH

or a pharmaceutically acceptable salt thereof.

Claim 17 recites "A method for reducing blood glucose levels in a mammal suffering from diabetes," comprising administering an effective amount of the same composition recited in claim 14 to the mammal. Claims 26 and 29 limit the composition administered in claims 14 and 17, respectively, to compound 1436.

Claims 14-30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Zasloff I² or Zasloff II³ in view of Merck⁴ (Ans.⁵ 3). Zasloff I and II both disclose administering compound 1436 to protect against cardiac ischemia (Zasloff I 5:20-22; Zasloff II 5:20-22). Zasloff I and II also both disclose that administration of aminosterols, e.g., compound 1436, causes hyperglycemia in mice, raising blood glucose levels 2-3 times the normal level (Zasloff I 83:1-58; Zasloff II 79:13 through 80:2).

The Examiner accords the preamble of claims 14 and 17 "little patentable weight" and construes the claimed subject matter as "drawn to method [sic] of treating a mammal suffering from hypercholesteremia or diabetes" (Ans. 7). The Examiner finds that Zasloff I and II describe treating diabetes by inhibiting NHEs with aminosterols (Ans. 3-4). The Examiner further finds that Merck teaches elevated serum cholesterol, hypertension diabetes mellitus, and obesity are major risk factors for atherosclerosis (Ans. 5), and that atherosclerosis is a generic term for

² US Patent 5,792,635, "Method of Inhibiting the Sodium/Proton Exchanger NHE3 and Method of Inhibiting Growth by Administering Squalamine," issued 11 August 1998, to Zasloff ("Zasloff I").

³ US Patent 5,840,740, "Aminosterol Compounds and a Method of Treating Infection Using the Aminosterol Compounds," issued 24 November 1998, to Zasloff et al. ("Zasloff II").

⁴ THE MERCK MANUAL OF DIAGNOSIS AND THERAPY, seventeenth edition, Merck Research Laboratories (1999), 1654-57 ("Merck").

⁵ Examiner's Answer mailed 8 March 2007 ("Ans." 3).

diseases including cardiac infarction and diabetes (Ans. 4-5). The Examiner concludes that since serum cholesterol level is a major risk factor for atherosclerosis (Merck) and aminosterols have been shown to treat atherosclerosis (Zasloff I and II), a skilled artisan would have reasonably expected the recited aminosterols to treat hypercholesteremia (Ans. 7).

This appeal raises three questions for consideration. Should the preambles of claims 14 and 17 be given patentable weight? Would treatment of a disease state associated with multiple risk factors reasonably teach or suggest successful treatment of one specific risk factor? Would induction of high blood glucose levels in healthy mice with aminosterols reasonably teach or suggest using those same aminosterols to reduce blood glucose levels in diabetic mice?

First, if, "when read in the context of the entire claim," the preamble "is necessary 'to give life, meaning, and vitality' to" the claim, the preamble language is properly treated as limiting. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). Here, the preambles of claims 14 and 17 are necessary "to give life, meaning, and vitality" to the claims. For example, but for their respective preamble language, claims 14 and 17 would be duplicative claims. Furthermore, Appellants rely on the preamble claim language to distinguish over the prior art (Br. 6-9). Lastly, this construction is consistent with the '247 specification (see e.g., '247 Specification 5:16-20). Therefore, we construe claims 14 and 17 as reciting methods for "reducing blood cholesterol levels in a mammal suffering from hypercholesteremia" and "reducing blood glucose levels in a mammal suffering from diabetes," respectively, and not merely as methods for

administering the recited aminosterols to mammals having hypercholesteremia or diabetes.

Second, the Examiner has failed to set forth a sufficient factual basis for concluding that successful treatment of atherosclerosis generally, or the particular atherosclerotic diseases, e.g., diabetes, described in Zasloff I or II specifically, with selected aminosterols reasonably resulted from the aminosterols lowering one specific risk factor, i.e., high serum cholesterol levels, among a myriad of other risk factors for atherosclerosis. Indeed, Merck describes not only high serum cholesterol levels, but also age, sex, family history of premature atherosclerosis, elevated levels of low density lipoprotein, reduced levels of high density lipoprotein, hypertension, cigarette smoking, diabetes, obesity, lack of physical exercise, elevated blood homocysteine levels, and *Chlamydia pneumonia* infection as risk factors for atherosclerosis generally (Merck 1656-57). In rejecting claims under 35 U.S.C. § 103(a), it is incumbent upon the Examiner to establish a sufficient factual basis to support the legal conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988).

Third, the Examiner has not explained why a skilled artisan would have reasonably expected that aminosterols which increase blood glucose levels 2-3 times the normal level in non-diabetic mice would decrease blood glucose levels in diabetic mice. The Examiner's position is counterintuitive. Although the Examiner alludes to "treatment of diabetes, among many other diseases, through the inhibition of NHEs by aminosterols" (Ans. 7), the Examiner fails to explain the allusion. For example, the Examiner fails to explain what a skilled artisan would have understood the relationship between "NHEs" and diabetes (or hypercholesteremia) to be, which one or

more NHEs was involved in diabetes (or hypercholesteremia), expected differences and/or similarities in NHEs between diabetic and non-diabetic mammals (or mammals with and without hypercholesteremia), etc. In short, the Examiner has failed to establish a sufficient factual basis to support the legal conclusion of obviousness.

In conclusion, in view of the record and for the reasons given, it is

ORDERED that the rejection of claims 14-30 under 35 U.S.C.
§ 103(a) as obvious over Zasloff I or Zasloff II in view of Merck is
REVERSED.

REVERSED

yrt

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Application 09/885,247

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